



Product Service

# EC Certificate

## Full Quality Assurance System

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)  
(List A and B and devices for self-testing)

No. V1 17 01 63505 056

**Manufacturer:**

**OK Biotech Co., Ltd.**

No. 91, Sec. 2, Gongdao 5th Road  
30070 Hsinchu City  
TAIWAN

與正本相符



**EC-Representative:**

**Medical Device Safety Service GmbH**

Schiffgraben 41  
30175 Hannover  
GERMANY

**Product  
Category(ies):**

**Blood glucose measuring systems for self testing  
(Blood glucose monitoring system)**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device families in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of List A devices an additional Annex IV (4) certificate is mandatory. See also notes overleaf.



**Report No.:**

TW1700820

**Valid from:**

2017-03-30

**Valid until:**

2022-03-29

**Date,** 2017-03-24

Stefan Preiß



TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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**Model(s):**

Blpod Glucose Monitoring System:  
including Blood Glucose Meter  
Blood Glucose Test Strips & Control Solution  
Model Name:

- OKmeter
- OKmeter Voice
- OKmeter Match
- OKmeter Match II
- OKmeter Direct
- OKmeter Link
- OKmeter Cameo
- OKmeter Cameo Plus
- OKmeter Vita
- OKmeter AcePlus
- OKmeter Optima ( Model No. OK-10H-X(X=0~10))
- OKmeter Lumina ( Model No. OK-14V-X(X=0~10))
- OKmeter Premia ( Model No. OK-1R-X(X=0~10))
- OKmeter Hitech
- OKmeter Core
- iCare Advanced
- OKmeter Choice
- OKmeter Sure
- OKmeter SurePlus
- OKmeter Concept
- OKmeter EASY-TEST

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OK BIOTECH CO., LTD.

**Facility(ies):**

OK Biotech Co., Ltd.  
No. 91, Sec. 2, Gongdao 5th Road, 30070 Hsinchu City, TAIWAN